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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,420	08/15/2006	Tsukao Yokoyama	YPO1.001APC	9866

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EXAMINER	
GRUN, JAMES LESLIE	
ART UNIT	PAPER NUMBER
1641	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/589,420	YOKOYAMA ET AL.	
	Examiner	Art Unit	
	JAMES L. GRUN	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21 and 26-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21 and 26-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The amendment filed 10 May 2010 is acknowledged and has been entered. Claims 34-37 are newly added. Claims 1-20 and 22-25 have been cancelled. Claims 21 and 26-37 remain in the case.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Applicant's prior showing of the current ready commercial availability of the "NC1" antibody was sufficient to overcome a prior deposit requirement made in a previous Office action. Applicant is cautioned that the material required for practice of the method may cease to be known and readily available to the public at some future time. Public access during the term of a patent may affect the enforceability of that patent.

Claims 33 and 37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Johansson et al. (J. Biol. Chem. 267: 24533, 1992) teach populations of noncollagenous domains of collagen (NC1) in glomerular basement membranes. One would expect antibodies specific for NC1 to bind to NC1 in the glomerular basement membranes of kidney samples (see e.g. Figs. 1-4) regardless of whether the subject mammal providing the sample suffered from nephritis or not. Absent further description and guidance from applicant, one would have no assurance of practicing the method as claimed because one would not be able to discern anything regarding nephritis in the patient merely by detecting binding of an antibody to an antigen known or expected to be present in samples from all patients. Applicant's amendments necessitated the re-instatement of this rejection as made previously with regard to the prior similar subject matter of claims 25 and 29.

Claims 27 and 28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant teaches immunofluorescence or enzyme immunoassay for the determination of antibody binding in tissue sections. Applicant teaches ELISA, precipitation, or agglutination methods, inter alia, for determination of antigen-antibody binding in fluid samples. Absent further description and guidance from applicant, one would have no assurance of practicing the method as claimed because one would not be able to apply methods taught as suitable for fluid samples to a frozen tissue sample as is now claimed.

Claims 21 and 26-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As set forth in a prior Office action, the reference of Yokoyama et al. (Cell 35: 40, 2003), in light of the translation made of record, specifically teaches detection of circulating noncollagenous domain of collagen (NC1) antigen and antibodies specific for NC1 antigen in biological samples from patients for the determination of early stage glomerulonephritis or a risk therefor. Likewise, the instant specification (see e.g. pages 3-4) teaches diagnosis of early stage nephritis with urine or serum samples, teaching indirect immunofluorescent detection of NC1 antigen in kidney tissue samples of monkeys or humans already known to have nephritis or nephropathy to determine or select antibody with appropriate reactivity for the relevant epitope. Absent any showing of the timing of the appearance of significant levels of the epitope detected by the NC1 monoclonal antibody, Mono 12D, it would seem unknown and unpredictable that the antigen (or the particular epitope) would be detectable at detectably different levels in mammals with early stage disease and not only after disease has manifested in the hosts, i.e. at injury crisis as exemplified in the specification. Absent further guidance from applicant, one would not be assured of the predictable ability to perform the method as is now claimed with kidney tissue samples.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35-37 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 35-37, "the subject" lacks antecedent basis.

Applicant's arguments filed 10 May 2010 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above.

Applicant's arguments filed 10 May 2010 with respect to prior rejections of the claims under statutes other than 35 U.S.C. § 112, second paragraph, have also been fully considered but are moot in view of the new ground(s) of rejection set forth above.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Yokoyama et al. (Cell 35: 40, 2003), in light of the translation made of record, teach enzyme-linked immunosorbent immunoassays for the detection of circulating noncollagenous domain of collagen (NC1) antigen and antibodies specific for NC1 antigen in biological samples from patients with and without nephritis. Antigen and antibody detection is taught for the determination of early stage glomerulonephritis or a risk therefor. Levels of antigen and antibody were determined in both serum and urine samples. Urine samples are considered herein as a sample derived from kidney. The reference also teaches that an improvement of dialysis

therapy would involve the removal of NC1 antigen and antibodies specific for NC1 antigen from the glomerulonephritis patient during dialysis (see e.g. translation pages 7 and 8).

The Cosmo Bio Co. Ltd. references teach the commercial availability of the K35MONO anti-NC1 monoclonal antibody, which, absent evidence to the contrary, is identical to applicant's NC1 monoclonal antibody, Mono 12D, in view of applicant's specification at page 12.

Oftshun et al. (US 5,871,649) teach an affinity membrane device in a columnar shape for the removal of deleterious solutes such as autoantibodies in the blood of Goodpasture's syndrome patients (see e.g. col. 19).

Sugihara et al. (J. Pathol. 178: 352, 1996) teach anti-NC1 autoantibodies in the blood of patients with Goodpasture's syndrome, an anti-glomerular basement membrane antibody-induced glomerulonephritis autoimmune disease. The reference teaches at least one anti-NC1 monoclonal antibody.

Johansson et al. (J. Biol. Chem. 267: 24533, 1992) provided monoclonal and polyclonal antibodies to bovine glomerular basement membrane NC1 and used the antibodies in ELISA, Western blotting reactions, and in affinity columns for purification of NC1. In the ELISA, immobilized NC1 was used to capture the antibodies (an anti-NC1 antibody remover). The reference teaches populations of noncollagenous domains of collagen (NC1) in glomerular basement membranes.

Ninomiya et al. (J. Cell Biol. 130: 1219, 1995) teach monoclonal antibodies specific for NC1 peptides and their use in various immunoassays.

Borza et al. (J. Biol. Chem. 276: 28532, 2001) elicited monoclonal antibodies to bovine glomerular basement membrane that bound to NC1 in ELISA and were also used in Western

blotting reactions. The antibodies were used in affinity columns for purification of NC1 (a NC1 remover) and were used in immunoprecipitation assays with protein G-sepharose (an anti-NC1 antibody remover).

Yokoyama et al. (Cell 34: 36, 2002) teach induction of glomerulonephritis by injection of the NC1 domain of type IV collagen. The submitted translation is incomplete, however, and it is not clear if immunofluorescent immunohistochemical assays were used to detect glomerulonephritis.

Lan et al. (Clin. Exp. Immunol. 110: 233, 1997) teach glomerular crescent formation as an indicator of severe glomerular damage and disease.

Campbell teaches the general procedure for the production of monoclonal antibodies (pages 3-6) and that substituting a monoclonal antibody for a polyclonal antibody in an established immunoassay "is not novel and is obvious" (page 45).

Kitchell et al. (US 5,656,298) teach immunization with a primer dose and a delayed release booster dose five times that of the primer dose (see e.g. col. 14 and Fig. 7).

Chambers et al. (US 6,696,281) teach immunization with a primer dose and boosting with a higher dose than that of the primer dose for vaccination (see e.g. col. 62, Table 8).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 11 a.m. to 7 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, SPE, can be contacted at (571) 272-0806.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J. L. G./
James L. Grun, Ph.D.
Examiner, Art Unit 1641
July 19, 2010

/Mark L. Shibuya/
Supervisory Patent Examiner, Art Unit 1641